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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gina N. Shishima
Fulbright & Jaworski L.L.P.
Suite 2400
600 Congress Avenue
Austin, TX 78701

EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,987	TRONO ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *8,12,14-40,42-45 and 48-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-11, 13, 41, 46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/04; 11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-14, 41, 46 and 47, in the reply filed on 10/08/05 is acknowledged. Applicant's election with traverse of the TeT^R repressible promoter in claim 9, the promoter inducible by tetracycline or tetracycline analogue in claim 11 and the lentiviral vector in claim 3 in the reply filed on 10/08/05 is also acknowledged. The traversal is on the ground(s) that all claims 3, 9 and 11-14 are proper Markush groupings because all members of the group share a common utility and a substantial structural feature because all members of the group are "viral vectors" that have a common structural feature of being composed of nucleic acid. This is not found persuasive the common structural feature of being composed of nucleic acid is not a substantial structural feature disclosed as being essential to that utility, as set forth in the Action mailed 08/09/05 (pg. 17). Applicant is correct in assuming that the Requirement for Restriction set forth a request for all claims readable on the combination of elements required by the claimed polynucleotide construct, which are identified by Applicant on pg. 19 of the instant response, as claims 1-7, 9-11, 13, 41 and 46-47.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Application

2. Claims 1-84 are pending in this application. Claims 8, 12, 14-40, 42-45 and 48-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being

drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-7, 9-11, 13, 41, 46 and 47 are currently under examination.

Information Disclosure Statement

3. The information disclosure statement filed 2/26/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In particular, no copies of references C70-C303 are present in the Application file. Therefore, only references A1-A43, B1-B9 and C1-C69 have been considered on this IDS. This IDS has been placed in the application file, but the information referred to therein as references C70-C303 has not been considered.

Additionally, Reference B11 on the information disclosure statement filed 11/12/2004 has not been considered. The IDS fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (e.g., B11). It has been placed in the application file, but the information referred to therein as Reference B11 has not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6-7 and 9 each recite the limitation "The construct of claim 1, wherein the repressible promoter" in line 1 There is insufficient antecedent basis for this limitation in the claim because claim 1 is drawn to an externally controllable promoter, which may be inducible or repressible (as disclosed in the instant specification). Therefore, the scope of what is claimed in claims 6-7 and 9 cannot be determined without assumption.

6. Claims 41 and 46-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 41, the phrase "in accordance with " renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "in accordance with"), thereby rendering the scope of the claim(s) unascertainable. The skilled artisan cannot determine the metes and bounds of what is being claimed with this terminology, without assumption, because the claimed mammalian cell comprises a polynucleotide construct “in accordance” with claim 1, which may be the same construct or may be a similar

construct that is "in accordance." Claims 46-47 are rejected due to their dependence on a rejected claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 6-7, 9, 41 and 46-47 are considered indefinite for the reasons set forth above. However, for the purposes of prior art, a search of "repressible promoters" from claims 6-7 and 9 has been performed. Additionally, although the terminology, "in accordance with" renders claims 41, 46 and 47 indefinite for the reasons set forth above, a reasonable interpretation of what may be encompassed considers that "in accordance with" means that the polynucleotide construct in claim 41 is the same polynucleotide construct as set forth in claim 1. The following prior art is applied based on these interpretations.

9. Claims 1-7, 9-11, 13, 41, 46 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Lois-Caballe et al. (US 2003/0068821 which is supported by the disclosure of Provisional Application 60/389,592 filed 6/18/2002). The invention set forth in the instant claims is generally drawn to a polynucleotide construct that is a lentiviral vector that encodes an siRNA operably linked to an externally controllable promoter that is an inducible or repressible promoter that is regulated controlled by *tet*O (the tet operator). Lois-Caballe disclose a lentiviral vector construct that encodes an siRNA operably linked to an externally controllable promoter that is a Tet-inducible pol III promoter containing a Tet01 binding site wherein expression can be downregulated by a Tet repressor in response to doxycycline and can be unregulated (induced) by tetracycline (see in particular pg. 3, sections [0036-0037]; sections [0008-0014], [0022], [0053-0055], [0075]). Lois-Caballe disclose that their lentiviral vector can be used to transform mammalian cells, oocytes and stem cells (sections [0026] and [0101-0103].

Therefore, the instant invention as set forth in claims 1-7, 9-11, 13, 41, 46 and 47 is anticipated by Lois-Caballe et al.

10. Claims 1-2, 4-7, 9-11, 13, 41, 46 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Giordano et al. (EP 1 229 134 A2; Reference B10 on PTO Form 1449 filed 11/12/2004).

The invention set forth in the instant claims is outlined above.

Giordano et al. disclose the use of inducible and repressible transcription systems that can be used to control the timing of the expression of dsRNA from polynucleotide constructs that can be retroviral vectors which express siRNAs wherein the inducible and repressible transcription system can be the previously described Tet promoter (see sections: [0110], [0010-0012], [0049-0050] and [0073]). The disclosure of Giordano et al., of the Tet promoter inducible and repressible transcription system is reasonably considered an inherent disclosure of a repressible promoter regulated by the Tet repressor which comprises at least one *tet*O sequence (or it would not be repressible) that is antibiotic inducible by doxycycline (as known in the art, see previous rejection herein). Giordano et al. disclose the polynucleotide constructs of their invention as comprised in mammalian cells, stem cells and gametes (which is reasonably considered an inherent disclosure of both sperm and oocytes) (see section [0016]).

Therefore, the instant invention as set forth in claims 1-2, 4-7, 9-11, 13, 41, 46 and 47 is anticipated by Giordano et al.

11. Claims 1-2, 10, 13, 41, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Beach et al. (WO 01/68836).

The invention set forth in the instant claims is outlined above.

Beach et al. disclose the double stranded RNA constructs that can be 25 nucleotide duplexes that are transcribed from vectors that comprise inducible promoters operably linked to the encoded dsRNAs, wherein expression can be induced by an

externally applied agent that can be temperature (pg. 21; pg. 22, lines 24-36). Beach et al. disclose a method of inducing RNA interference in cells wherein the cells can be mammalian and from a germ line (which is reasonably considered an inherent disclosure of both sperm cells and oocytes), totipotent or stem cells (pg. 18; pg. 19, lines 5-25).

Therefore, the instant invention as set forth in claims 1-2, 10, 13, 41, 46 and 47 is anticipated by Beach et al.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-7, 9-11, 13, 41 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yao et al. (W0 99/00510), Verma et al. (US Patent 6,013,516; Reference A23 on PTO Form 1449 filed 02/26/04), Elbashir et al. (EMBO Journal, Vol., 20(23):6877-6888; published December 3rd 2001) and Elbashir et al. 2001 (Nature Vol., 411: pp. 494-498).

Claims 1-7, 9-11, 13, 41 and 46-47 are drawn to a polynucleotide construct comprising a region encoding a siRNA operably linked to an externally controllable promoter (claim 1) that is a vector (claim 2) that is a lentiviral vector (claim 3) wherein the promoter is repressible by means of an externally applied agent that is an externally applied drug (claims 4-5) wherein the repressible promoter is regulated by a Tet repressor and comprises at least one *tet*O sequence (claims 6-7) and is from the TeT^R gene (claim 9) wherein the promoter is an inducible promoter by means of an externally applied agent that is tetracycline or tetracycline analogue (claims 10-11) wherein the inducible promoter is inducible as listed in claim 13 and to a mammalian cell comprising the polynucleotide construct of claim 1 (claim 41) wherein the cell is an undifferentiated cell (claim 46) or an oocyte (claim 47)

Yao et al. teach DNA constructs suitable for gene expression in mammalian cells which are characterized by the presence of a mammalian promoter under control of a Tet operator/repressor system and that this Tet operator/repressor system can be used to engineer viruses as vehicles for the delivery of nucleic acids that can serve as therapeutic agents including antisense nucleic acids that bind and inhibit protein

expression (Abstract, pg. 2, line 20 – pg. 3, line 17; pg. 20 "D"). Yao et al. teach recombinant DNA molecules, the expression of which is under control of a repressible or inducible mammalian promoter that is regulated by a Tet operator sequence (pg. 13, lines 4-25). Yao et al. teach the typical incorporation of their polynucleotide constructs into viral vectors that can be retroviruses (pg. 10, line 1). Yao et al. teach the transduction of mammalian stem cells with the polynucleotide constructs and vectors of their invention (pg. 15). Yao et al. teach that by combining transdominant negative mutant viral polypeptides with the Tet^R-regulated potent mammalian transcription switch, a novel viral replication switch can be generated and that in principle, any polypeptide or antisense RNA that is capable of inhibiting viral productive infection can be incorporated into the novel viral replication switch. The disclosure of Yao et al., therefore, is reasonably considered a disclosure of a polynucleotide construct that expresses a nucleic acid therapeutic that can be an antisense RNA wherein the expressed nucleic acid is operably linked to an externally controllable promoter that is a repressible promoter that can be down regulated by means of externally applied agent or drug (because the Tet operator can be down regulated by external application of doxycycline or the Tet repressor protein) that is regulated by a Tet repressor wherein the repressible promoter is from the TeT^R gene (see figure 2, for example) and a disclosure of an inducible promoter that can be unregulated by an externally applied agent that is tetracycline.

Yao et al. do not teach the expression of siRNAs from the polynucleotide constructs of their invention or specifically recite lentiviral vectors.

Verma et al. (US Patent 6,013,516) disclose lentiviral vectors that express heterologous nucleic acid sequences that are operably linked to a regulatory nucleic acid sequence that can be a promoter and that a wide range of promoters, including suitable viral and mammalian promoters are known in the art (col. 6, lines 24-29). Verma et al. disclose that the lentiviral vectors of their invention can be used to express antisense nucleic acids and ribozymes to inhibit gene expression in mammalian cells (col. 7).

Elbashir et al. teach a systematic analysis of the length, secondary structure, sugar backbone and sequence specificity of siRNA duplexes used for RNAi in Drosophila and the structure of the most potent siRNA duplexes that are 21 nt long comprising a 19 nt base paired sequence with 2 nt 3' overhanging ends (see "siRNA users guide": pg. 6885). Elbashir et al. teach that siRNAs are valuable reagents for inactivation of gene expression, not only in insect cells but also in mammalian cells, with great potential for therapeutic application (pg. 6884, col. 2).

Elbashir et al. (Nature) teach that the mediators of sequence specific messenger RNA degradation in mammalian cells are 21 and 22 nucleotide small interfering RNAs, that 21 nucleotide siRNA duplexes specifically express expression of endogenous and heterologous genes in different mammalian cell lines and that therefore 21 nt siRNAs provide a new tool for studying gene function (Abstract). Elbashir et al. teach that siRNAs are extraordinarily powerful reagents for mediating gene silencing and that siRNAs are effective at concentrations that are several orders of magnitude below the

concentrations applied in conventional antisense or ribozyme gene targeting experiments (pg. 496, col. 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to formulate a polynucleotide construct comprising a region encoding a siRNA operably linked to an externally controllable promoter that was a lentiviral vector construct that comprised a Tet operator/repressor system (as taught by Yao et al., Elbashir et al. and Verma et al.) wherein the externally controllable promoter was repressible by means of an externally applied agent that is an externally applied drug, wherein the repressible promoter was regulated by a Tet repressor and comprises at least one *tet*O sequence and is from the TeT^R gene (as taught by Yao et al.) wherein the promoter is an inducible promoter by means of an externally applied agent that is tetracycline or tetracycline analogue (as taught by Yao et al.) in order to transduce mammalian stem cells (as taught by Yao et al.) to study gene function (as taught by Elbashir et al.

One of ordinary skill in the art would have been motivated to construct a polynucleotide construct comprising a region encoding a siRNA operably linked to an externally controllable promoter that was a lentiviral vector construct that comprised a Tet operator/repressor system in order to study gene function in a mammalian cell by controlling the expression of an siRNA (as taught by Elbashir et al., Yao et al. and Verma et al.).

One of ordinary skill in the art would have expected success in constructing a polynucleotide construct comprising a region encoding a siRNA operably linked to an

externally controllable promoter that was a lentiviral vector construct that comprised a Tet operator/repressor system because the functional anatomy of siRNAs that are effective in mammalian cells was known, because the siRNAs described by Elbashir et al. provide a new tool for studying gene function, because siRNAs are extraordinarily powerful reagents for mediating gene silencing and are effective at concentrations that are several orders of magnitude below the concentrations applied in conventional antisense or ribozyme gene targeting experiments (as taught by Elbashir et al.), because Yao et al. teach the successful construction of the above polynucleotide construct in a retroviral vector, because lentiviral vectors are retroviral vectors that are taught by Verma et al. as viral vectors that will express heterologous nucleic acid sequences that are operably linked to a regulatory nucleic acid sequence that can be any of a wide range of promoters, including suitable viral and mammalian promoters that are known in the art, and because Verma et al. teach that lentiviral vectors can be used to express antisense nucleic acids and ribozymes to inhibit gene expression in mammalian cells.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

15. Claims 1-7, 9-11, 13, 41 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giordano et al., Elbashir et al. 2001 (EMBO Journal) and Elbashir et

al. 2001 (Nature) as applied to claims 1-2, 4-7, 9-11, 13, 41, 46 and 47 above, and further in view of Verma et al. (US Patent 6,013,516).

The teachings of Giordano et al. are relied upon as above (see rejecting under 35 U.S.C. § 102(a)).

The teachings of Elbashir et al. 2001 (EMBO Journal) are relied upon as above.

The teachings of Elbashir et al. 2001 (Nature) are relied upon as above.

The teachings of Verma et al. (US Patent 6,013,516) are relied upon as above.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to formulate a polynucleotide construct comprising a region encoding a siRNA (as taught by Elbashir et al.) operably linked to an externally controllable promoter that was a lentiviral vector construct that comprised a Tet operator/repressor system (as taught by Giordano et al. and Verma et al.) wherein the externally controllable promoter was repressible by means of an externally applied agent that is an externally applied drug, wherein the repressible promoter was regulated by a Tet repressor and comprises at least one *tet*O sequence and is from the TeT^R gene wherein the promoter is an inducible promoter by means of an externally applied agent that is tetracycline or tetracycline analogue, in order to transduce mammalian stem cells (as taught by Giordano et al.) for the purposes of studying gene function, particularly in differentiating stem cells (as taught by Giordano et al. and Elbashir et al.).

One of ordinary skill in the art would have been motivated to construct a polynucleotide construct comprising a region encoding a siRNA operably linked to an externally controllable promoter that was a lentiviral vector construct that comprised a

Tet operator/repressor system in order to study gene function in a mammalian cell by controlling the expression of an siRNA (as taught by Giordano et al., Elbashir et al., and Verma et al.).

One of ordinary skill in the art would have expected success in constructing a polynucleotide construct comprising a region encoding a siRNA operably linked to an externally controllable promoter that was a lentiviral vector construct that comprised a Tet operator/repressor system because the functional anatomy of siRNAs that are effective in mammalian cells was known, because the siRNAs described by Elbashir et al. provide a new tool for studying gene function, because siRNAs are extraordinarily powerful reagents for mediating gene silencing (as taught by Elbashir et al.), because Giordano et al. teach the successful construction of the above polynucleotide construct to express a dsRNA in a vector, because Elbashir et al. teach the particular structure of successful siRNAs in mammalian cells, because lentiviral vectors are retroviral vectors that are taught by Verma et al. as viral vectors that will express heterologous nucleic acid sequences that are operably linked to a regulatory nucleic acid sequence that can be any of a wide range of promoters, including suitable viral and mammalian promoters that are known in the art, and because Verma et al. teach that lentiviral vectors can be used to express antisense nucleic acids and ribozymes to inhibit gene expression in mammalian cells. Therefore, one of skill would have expected success in formulating a retroviral vector for inducible or repressible control of expression of siRNAs in mammalian cells using the Tet operator system, wherein the mammalian cells were undifferentiated cells or oocytes (as taught by Giordano et al.) wherein the vector was a

lentiviral vector known to be effective at delivering and expressing nucleic acids to mammalian cells (as taught by Verma et al.).

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba

Jane Zara
TC 1600